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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

[Docket No. 00D–1679]

Compliance Policy Guidance for FDA Staff and Industry on Blood Donor Classification Statement, Paid or Volunteer Donor; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Blood Donor Classification Statements, Paid or Volunteer Donor," dated May 7, 2002. The guidance document provides guidance to FDA staff and industry for determining when blood or blood components should be labeled with a "paid donor" or "volunteer donor" classification statement. The document is intended to assist industry in determining when a donor incentive is considered a monetary payment, and to assist FDA employees in inspecting blood centers. This guidance finalizes the document entitled "Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives," published in the **Federal Register** of January 16, 2001 (66 FR 3605).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this compliance policy guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. You may fax your request to 301–827–0852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0410.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance policy guidance document entitled "Blood Donor Classification Statements, Paid or Volunteer Donor," dated May 7, 2002. The guidance document provides information to industry and FDA employees regarding when a blood donor incentive would require the blood or blood component to be labeled with a "paid donor" or "volunteer donor" classification statement.

In the **Federal Register** of January 13, 1978 (43 FR 2142), FDA published a final rule requiring that blood and blood components intended for transfusion include a statement on the labels that indicated whether the products were collected from a paid or volunteer donor (§ 606.121(c)(5) (21 CFR 606.121(c)(5))). The regulation defines a "paid donor" as a person who receives monetary payment for blood donation (§ 606.121(c)(5)(i)). A volunteer donor is a person who does not receive monetary payment for blood donation (§ 606.121(c)(5)(ii)).

The requirement for a donor classification statement applies only to blood and blood components intended for transfusion. It does not apply to blood and blood components intended for further manufacturing, such as Source Plasma.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash. This guidance document provides FDA employees and industry with the factors that FDA uses to evaluate incentives, and provides some examples of incentives that the Center for Biologics Evaluation and Research has evaluated in the past.

This guidance finalizes the draft guidance entitled "Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives" (66 FR 3605). The title of the document was changed to more accurately reflect its contents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on blood donor classification statements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Discussion of Comments

The agency received a number of comments on the draft compliance policy guidance (66 FR 3605). All of the comments were considered when preparing the final document.

Some of the comments requested further guidance on blood donor incentives that was outside of the scope of this document. FDA will consider issuing further guidance on the subject of blood donor incentives in the future.

IV. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ora/compliance_ref/cpg/default.htm.

Dated: 05/07/02
May 7, 2002.

Dennis E. Baker,
Associate Commissioner for Regulatory Affairs.

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